

Remarks

Support for the Amendments

The foregoing amendment to the specification is sought to correct an inadvertent typographical error. Therefore, this amendment does not add new matter.

Status of the Claims

Claims 2-29 are pending in the application, with claims 2-4, 20 and 21 being the independent claims.

Summary of the Office Action

In the Office Action dated November 17, 2004, the Examiner has made two rejections of the claims. Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

The Rejection Under 35 U.S.C. § 112, Second Paragraph

In the Office Action at page 2, the Examiner has rejected claims 2-29 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicant respectfully traverse this rejection.

The Examiner asserts that claims 2-29 are vague and indefinite in that the metes and bounds of "recombination sites or portions thereof" are unclear, asserting further that the structural requirements of the primers are unclear. Applicants respectfully disagree with these assertions.

Applicants submit that the ordinarily skilled artisan, upon reading the present specification, would readily understand that the term "recombination site" refers to a site-specific recombination site. The term "recombination site" was well known in the art at the time of the filing of the present application to mean a site-specific recombination site (*see e.g.*, U.S. Patent Nos. 5,888,732 and 6,171,861). The term "recombination site" is used in this context and with this meaning consistently throughout the present specification (*see, e.g.*, pages 32-47). Hence, one of ordinary skill in the art would readily understand the meaning of the term "recombination site" as it is used in the present claims.

With regard to the term "portions thereof" as it relates to recombination sites, the Examiner is directed to the present specification at page 28, paragraph 133, where the term "portions of recombination sites" is defined. "Portions of recombination sites comprise at least 2 bases, at least 5 bases, at least 10 bases or at least 20 bases of the recombination sites of interest." Specification at page 28, paragraph 133, lines 5-7. Based on this definition, Applicants respectfully submit that the ordinarily skilled artisan would readily understand the term "portions thereof" as it is used in the present claims with respect to recombination sites.

In view of the foregoing remarks, Applicants respectfully submit that the present claims clearly point out and distinctly claim the subject matter which Applicants regard as the invention. Reconsideration and withdrawal of the rejection of claims 2-29 under 35 U.S.C. § 112, second paragraph, are respectfully requested.

The Rejection Under 35 U.S.C. § 103, Over Hartley in View of Shuman

In the Office Action at pages 2-5, the Examiner has rejected claims 2-29 as being allegedly being unpatentable over Hartley *et al.* (WO 96/40724; hereinafter "Hartley") in view of Shuman (U.S. Patent No. 5,766,891; hereinafter "Shuman"). Applicants respectfully traverse this rejection.

The Examiner states:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate the double-stranded molecules to be used in recombination by Hartley *et al.* with the method of PCR taught by Shuman because Hartley *et al.* teach that it is within the ordinary skill of the art to use double-stranded molecules with recombination sites at either end for recombinational cloning and because Shuman teaches that it is within the ordinary skill of the art to generate double-stranded molecules for cloning using PCR. One would have been motivated to do so in order to receive the expected benefit of generating sub-cloning systems that are highly specific, rapid and less labor intensive.

Office Action at page 4, third full paragraph, lines 1-8.

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *See In re Piasecki*, 223USPQ 785, 787-88 (Fed. Cir. 1984). The Examiner can satisfy this burden only by showing some objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teachings of the references in such a way as to produce the invention as claimed. *See In re Fine*, 5 USPQ2d 1596,1598 (Fed. Cir. 1988). There is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time the invention was made. *See Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1995). Instead, what is needed is a reason, suggestion,

or motivation in the prior art that would motivate one of ordinary skill to combine the cited references, and that would also suggest a reasonable likelihood of success in making or using the claimed invention as a result of that combination. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). In the present case, the Examiner's burden has not been satisfied.

The fact that Hartley discloses sequences for recombination, while Shuman describes the use of primers with specific unrelated sequences, does not render the present claims obvious. As noted above, absent some suggestion and/or motivation, the cited references may not be properly combined to render the claimed invention obvious. *See In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Here, the Examiner states the ordinarily skilled artisan would have been motivated to combine the cited references based merely on the "expected benefit" of generating less labor intensive sub-cloning systems. Applicants respectfully submit that the Examiner has not provided any suggestion or motivation to combine the references based upon the references themselves. According to the Federal Circuit, there are three permissible sources for a motivation to combine references: "the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *See In re Rouffet*, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Applicants respectfully contend that the Examiner has not shown any of these sources to be present in the cited references, which therefore may not be properly combined under *Fine*. 5 USPQ2d 1596 (Fed. Cir. 1988).

The fact that Hartley and Shuman were in existence at the time the instant application was filed, without more, is not sufficient for a finding of obviousness. The Examiner has not pointed to anything in Hartley or Shuman which provides any motivation to combine their disclosures. Thus, the Examiner has not met the burden required to sustain a *prima*

facie case of obviousness. In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 2-29 under 35 U.S.C. § 103(a).

Conclusion

All of the stated grounds of rejection have been properly traversed. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn, and that all pending claims be allowed.

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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